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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Brian Leyland-Jones
Application No.: 10/607,848 Group Art Unit: 1641
Filed: June 27, 2003 Examiner: David J. Venci
Confirmation No.: 4832
Title: Individualization of Therapy with Anticoagulants

CERTIFICATE OF MAILING OR TRANSMISSION	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, or is being facsimile transmitted to the United States Patent and Trademark Office on:	
Date: 7-21-05	Signature: <i>Dawn M. Myers</i>
Typed or printed name of person signing certificate: <i>Dawn M. Myers</i>	

INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

☐ under 37 CFR 1.129(a), or

(First/Second submission after Final Rejection)

☒ under 37 CFR 1.97(b), or

(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

☐ under 37 CFR 1.97(c) together with either:

☐ a Statement under 37 CFR 1.97(e), as checked below, or

☐ a \$180.00 fee under 37 CFR 1.17(p), or

(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

☐ under 37 CFR 1.97(d) together with:

☐ a Statement under 37 CFR 1.97(e), as checked below, and

☐ a \$180.00 fee under 37 CFR 1.17(p), or

(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

☐ under 37 CFR 1.97(i):

Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.

(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
 - ☒ Copies of the cited references AL-AO, AR-AT2 and AU2-AW2 are enclosed.
 - ☒ Copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
 - ☐ Copies of the cited references are enclosed except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]
 - ☒ The listed references (AN, AX, AO, AU2 and AV2) were cited in the enclosed International Search Report in a counterpart foreign application.
 - ☐ The "concise explanation" requirement (non-English references) for reference(s) [] under 37 CFR 1.98(a)(3) is satisfied by:
 - ☐ the explanation provided on the attached sheet.
 - ☐ the explanation provided in the Specification.
 - ☐ submission of the enclosed International Search Report.
 - ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
 - ☐ the enclosed English language abstract.

☐ Applicant requests that the following non-published pending applications be considered:

Examiner's
Initials

____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []
____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []
____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

Examiner

Date

- ☐ A copy of each above-cited application, including the current claims, is enclosed.
- ☐ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

- ☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- ☐ Please charge Deposit Account 08-0380 in the amount of \$[]. A copy of this Statement is enclosed.
- ☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By Deirdre E. Sanders

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Concord, MA 01742-9133

Dated: July 21, 2005

PTO-1449 REPRODUCED

**INFORMATION DISCLOSURE CITATION
IN AN APPLICATION**

July 21, 2005

(Use several sheets if necessary)

 ATTORNEY DOCKET NO.
3287.1005-000

 APPLICATION NO.
10/607,848

 FIRST NAMED INVENTOR
Brian Leyland-Jones

 FILING DATE
June 27, 2003

 EXAMINER
David J. Venci

 CONFIRMATION NO.
4832

 GROUP
1641

U.S. PATENT DOCUMENTS

EX- AMINER INI- TIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	AA	5,786,220	07-28-1998	Pronovost, <i>et al.</i>
	AB	6,287,765 B1	09-11-2001	Cubicciotti
	AC	5,830,672	11-03-1998	Wainer, <i>et al.</i>
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EXAMINER

DATE CONSIDERED

PTO-1449 REPRODUCED INFORMATION DISCLOSURE CITATION IN AN APPLICATION July 21, 2005 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 3287.1005-000		APPLICATION NO. 10/607,848	
	FIRST NAMED INVENTOR Brian Leyland-Jones		FILING DATE June 27, 2003	
	EXAMINER David J. Venci		CONFIRMATION NO. 4832	GROUP 1641

FOREIGN PATENT DOCUMENTS						
		DOCUMENT NUMBER Country Code-Number-Kind Code (if known)	DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	TRANSLATION YES NO	
	AL	EP 0 921 396 A2	06-09-1999	Pfizer Products Inc.		
	AM	WO 01/11035 A1	02-15-2001	Merck & Co., Inc.		
	AN	WO 00/55624	09-21-2000	Brian Leyland-Jones and Pierre Wong		
	AO	WO 95/04757	02-16-1995	Board of Regents, The University of Texas System		
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EXAMINER	DATE CONSIDERED
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PTO-1449 REPRODUCED INFORMATION DISCLOSURE CITATION IN AN APPLICATION July 21, 2005 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 3287.1005-000		APPLICATION NO. 10/607,848	
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	EXAMINER David J. Venci		CONFIRMATION NO. 4832	GROUP 1641

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AR	Beste, G., <i>et al.</i> , "Small Antibody-Like Proteins With Prescribed Ligand Specificities Derived From The Lipocalin Fold," <i>Proc. Natl. Acad. Sci.</i> , 96:1898-1903 (1999).
AS	Rabbany, S. Y., <i>et al.</i> , "Optical Immunosensors," <i>Crit. Rev. Biomed. Eng.</i> , 22(5/6):307-346 (1994).
AT	Wang, J., <i>et al.</i> , "Mismatch-Sensitive Hybridization Detection by Peptide Nucleic Acids Immobilized on a Quartz Crystal Microbalance," <i>Anal. Chem.</i> , 69:5200-5202 (1997).
AU	Wong, P., <i>et al.</i> , "A Competitive Enzyme Linked Immunosorbent Assay for the Determination of <i>N</i> -Acetyltransferase (NAT2) Phenotypes," <i>J. Pharm. Biomed. Anal.</i> , 13:1079-1086 (1995).
AV	Desta, Z., <i>et al.</i> , "Effect of Clarithromycin on the Pharmacokinetics and Pharmacodynamics of Pimozide in Healthy Poor and Extensive Metabolizers of Cytochrome P450 2D6 (CYP2D6)," <i>Clin. Pharmacol. Ther.</i> , 65(1):10-20 (1999).
AW	Tang, B. K., <i>et al.</i> , "Caffeine as a Metabolic Probe: Validation of its Use for Acetylator Phenotyping," <i>Clin. Pharmacol. Ther.</i> , 49(6):648-657 (1991).
AX	Wong, P.N., <i>et al.</i> "Syntheses of Caffeine Metabolites Derivatives for Measuring CYP1A2 Activity by ELISA," Proceedings of the 90th Annual Meeting of the American Association for Cancer Research, 40:53 (1999).
AY	Wolf, C. R., <i>et al.</i> , "Chapter 18. Cytochrome P450 CYP2D6," <i>Metabolic Polymorphisms and Susceptibility to Cancer</i> , 148:209-229 (1999).
AZ	Kroemer, H. K., <i>et al.</i> , "It's the Genes, Stupid', Molecular Bases and Clinical Consequences of Genetic Cytochrome P450 2D6 Polymorphism," <i>Life Sci.</i> , 56(26):2285-2298 (1995).
AR2	Kenworthy, K. E., <i>et al.</i> , "CYP3A4 Drug Interactions: Correlation of 10 <i>In Vitro</i> Probe Substrates," <i>Br. J. Clin. Pharmacol.</i> , 48:716-727 (1999).
AS2	Hirth, J., <i>et al.</i> , "The Effect of an Individual's Cytochrome CYP3A4 Activity on Docetaxel Clearance," <i>Clin. Cancer Res.</i> , 6:1255-1258 (2000).
AT2	Thummel, K. E., <i>et al.</i> , " <i>In Vitro</i> and <i>In Vivo</i> Drug Interactions Involving Human CYP3A," <i>Annu. Rev. Pharmacol. Toxicol.</i> , 38:389-430 (1998).

EXAMINER

DATE CONSIDERED

PTO-1449 REPRODUCED INFORMATION DISCLOSURE CITATION IN AN APPLICATION July 21, 2005 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 3287.1005-000		APPLICATION NO. 10/607,848	
	FIRST NAMED INVENTOR Brian Leyland-Jones		FILING DATE June 27, 2003	
	EXAMINER David J. Venci	CONFIRMATION NO. 4832	GROUP 1641	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	AU2	Innocenti, F., <i>et al.</i> "Pharmacogenetics of Anticancer Agents: Lessons from Amonafide and Irinotecan," <i>Drug Metabolism and Disposition</i> , 29(4): 596-600 (2001).
	AV2	Iyer, L. and Ratain, M.J., "Pharmacogenetics and Cancer Chemotherapy," <i>European Journal of Cancer</i> , 34(10):1493-1499 (1998).
	AW2	Ratain, <i>et al.</i> "Phase I Study of Amonafide Dosing Based on Acetylator Phenotype," <i>Cancer Research</i> , 53: 2304-2308 (1993).

EXAMINER	DATE CONSIDERED
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